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TRANSMITTAL LETTER			
Serial No. 09/839,684	Filing Date April 19, 2001	Examiner To be assigned	Case No. 10466/18 Group Art Unit 1615
Inventor(s) Franklin Okumu			
Title of Invention SUSTAINED RELEASE FORMULATIONS			

## TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an Information Disclosure Statement; Form PTO-1449; 64 cited references and reclaim postcard.

Small entity status of this application under 37 CFR § 1.27 has been established by verified statement previously submitted.

☐

A verified statement to establish small entity status under 37 CFR §§ 1.9 and 1.27 is enclosed.

☐

Petition for a \_\_\_\_\_ month extension of time.

☒

No additional fee is required.

☐

The fee has been calculated as shown below:

	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra
Total		Minus		
Indep.		Minus		
First Presentation of Multiple Dep. Claim				

## Small Entity

Rate	Add'l Fee
x \$9 =	
x 42 =	
+ \$140 =	
Total add'l fee	\$

or

## Other Than Small Entity

Rate	Add'l Fee
x \$18 =	
x \$84 =	
+ \$280 =	
Total add'l fee	\$

☐

Please charge Deposit Account No. 23-1925 (BRINKS HOFER GILSON & LIONE) in the amount of \$\_\_\_\_\_. A duplicate copy of this sheet is enclosed.

☐

A check in the amount of \$\_\_\_\_\_ to cover the filing fee is enclosed.

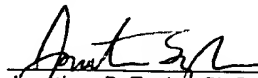
☒

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this communication or credit any overpayment to Deposit Account No. 23-1925. A duplicate copy of this sheet is enclosed.

☒

I hereby petition under 37 CFR § 1.136(a) for any extension of time required to ensure that this paper is timely filed. Please charge any associated fees which have not otherwise been paid to Deposit Account No. 23-1925. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

  
Jonathan P. Taylor, Ph.D.  
Registration No. 48,338  
Agent for Applicant

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4200

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on October 8, 2001.

Date: 10/8/01

Signature: 



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, with sufficient postage, addressed to: Commissioner for Patents, Washington, D.C. 20231, on

October 8, 2001

Date of Deposit

Jonathan P. Taylor, Ph.D.

Name of Applicant, Assignee or  
Registered Representative

*Jonathan P. Taylor*  
Signature

10/8/01

Date of Signature

IDS #6 3/12/02  
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Our Case No.: 10466/18

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Franklin Okumu

Serial No.: 09/839,684

Filing Date: April 19, 2001

For: SUSTAINED RELEASE  
FORMULATIONS

Examiner: To be assigned

Group Art Unit No.: 1615

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed below and on the attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

The references now cited are the following:

No.	Dat	Name
4,297,344	10/27/1981	Schwinn et al.
4,938,763	7/3/1990	Dunn et al.
4,975,271	12/4/1990	Dunn et al.
5,077,049	12/31/1991	Dunn et al.
5,096,885	3/17/1992	Pearlman et al.
5,133,981	7/28/1992	Harkrader et al.
5,242,910	9/7/1993	Damanj
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5,589,167	12/31/1996	Cleland et al.
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6,051,259	4/18/2000	Johnson et al.
6,066,619	5/23/2000	Stevenson et al.
6,080,429	6/27/2000	Cleland et al.
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6,130,200	10/10/2000	Brodbeck et al.
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6,146,662	11/14/2000	Jao et al.
6,165,508	12/26/2000	Tracy et al.
6,174,547 B1	1/16/2001	Dong et al.
6,190,700 B1	2/20/2001	Okada et al.
6,191,107 B1	2/20/2001	Yamagata et al.

6,197,350 B1	3/6/2001	Yamagata et al.
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### **FOREIGN DOCUMENTS**

<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTRY</b>
WO 89/03671	5/5/1989	WIPO
O 484 387 B1	1/19/1994	Europe
MX 173182 A	7/2/1994	Mexico
WO 98/27963 A2	7/2/1998	WIPO
WO 98/27962 A2	7/2/1998	WIPO

### **OTHER ART**

1. Gray et al., "Cloning of Human Tumor Necrosis Factor (TNF) Receptor cDNA and Expression of Recombinant Soluble TNF-Binding Protein", *Proc. Natl. Acad. Sci. USA*, 87, 7380-7384 (1990)
2. Kohno et al., "A Second Tumor Necrosis Factor Receptor Gene Product Can Shed a Naturally Occurring Tumor Necrosis Factor Inhibitor", *Proc. Natl. Acad. Sci. USA*, 87, 8331-8335 (1990)
3. Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations", *Pharmaceutical Research*, 8, No. 3, 285-291 (1991)
4. Serge N. Timasheff, "The Control of Protein Stability and Association by Weak Interactions with Water: How Do Solvents Affect These Processes?" *Annu. Rev. Biophys. Biomol. Struct.*, 22, 67-97 (1993)
5. Kita et al., "Contribution of the Surface Free Energy Perturbation to Protein-Solvent Interactions", *Biochemistry*, 33, 15178-15189 (1994)

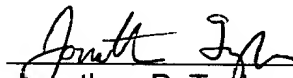
6. Serge N. Timasheff, "Solvent Stabilization of Protein Structure", *Methods in Molecular Biology*, 40, 253-269 (1995)
7. Lin et al., "On the Role of Surface Tension in the Stabilization of Globular Proteins", *Protein Science*, 5, 372-381 (1996)
8. Xie et al., "The Thermodynamic Mechanism of Protein Stabilization by Trehalose", *Biophysical Chemistry*, 64, 25-43 (1997)
9. Serge N. Timasheff, "Control of Protein Stability and Reactions by Weakly Interacting Cosolvents: The Simplicity of the Complicated", *Advances in Protein Chemistry*, 51, 355-432 (1998)
10. Johnson et al., "A Month-Long Effect From a Single Injection of Microencapsulated Human Growth Hormone", *Nature Medicine*, 2, No. 7, 795-799 (1996)
11. Sackett et al., "Multivalent Cations Depress Ligand Binding to Cell-Associated Insulin-Like Growth Factor Binding Protein-5 on Human Glioblastoma Cells", *Endocrinology*, 139, No. 4, 1943-1951 (1998)
12. Maa et al., "Spray-Drying of Air-Liquid Interface Sensitive Recombinant Human Growth Hormone", *Journal of Pharmaceutical Sciences*, 87, No. 2, 152-159 (1998)
13. Lai et al., "Metal and RNA Binding Properties of the hdm2 Ring Finger Domain", *Biochemistry*, 37, No. 48, 17005-17015 (1998)
14. Smith et al., "A Novel Parenteral Delivery System", *Pharmaceutical Research*, 13, No. 3, 300 (1996)
15. Yang et al., "Effect of Zinc Binding and Precipitation on Structures of Recombinant Human Growth Hormone and Nerve Growth Factor", *Journal of Pharmaceutical Sciences*, 89, No. 11, 1480-1485 (2000)

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement is being filed prior to the receipt of the first Official Action reflecting an examination on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these material, the Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson & Lione Deposit Account No. 23-1925. A duplicate copy of this document is enclosed.

Applicant(s) respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

  
Jonathan P. Taylor, Ph.D.  
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Agent for Applicant(s)

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